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October 8, 2024

VIA ECF
Honorable Renée Marie Bumb
United States District Court
Mitchell H. Cohen Building and
U.S. Courthouse
Courtroom 3D
4th and Cooper Streets
Camden, New Jersey 08101

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, MDL No. 19-2875 (RMB)

Dear Chief Judge Bumb:

Dr. Chodosh was disclosed by Defendants as an expert on general causation of cancer in patients consuming Valsartan Containing Drugs ("VCDs") contaminated with the genotoxic carcinogens, NDMA and NDEA. Dr. Chodosh's opinions are summarized in his August 2, 2021 report's conclusion: "As such, it is my conclusion, to a reasonable degree of medical and scientific certainty, that **exposure to NDMA and/or NDEA in valsartan, at the doses to which Plaintiffs**

were potentially exposed, and for the durations to which Plaintiffs were potentially exposed, would not cause cancer in human beings." (Chodosh Rep., at p. 63). Dr. Chodosh only analyzes issues of cancer causation and the doses necessary in his opinion to cause cancer.

Defendants now argue that the Court should permit the general causation testimony of Dr. Chodosh in an economic loss trial governed by the applicable regulatory standards addressing whether the risk posed by an unapproved genotoxic impurity is acceptable or not—where causation of cancer is irrelevant. This testimony should be precluded because, by his own admission, he addressed biological causation, NOT the more conservative regulatory standard predicated on risk, thus his opinions do not "fit" the legal and factual questions at issue in this economic loss trial. Otherwise, the jury will be misled into believing that the regulatory standards which controlled this situation, and deemed the contamination an unacceptable risk requiring a recall and import ban, can be pushed aside and ignored if the jury finds that the higher standard of general causation is not met. The jury cannot be permitted to apply the wrong legal standard in determining the damages that flow from the sale of drugs containing unapproved genotoxic impurities.

The deposition testimony of Dr. Chodosh quoted in Defendants' brief draws a bright line that highlights this critical distinction and demonstrates that he is not qualified to, and did not address the regulatory issues that will be presented in this trial:

> **So you're talking about regulatory issues for calculating safe doses, which is not my domain,** other than to say for genotoxic carcinogens the FDA guidance on their -- with a safety mandate is to use linear low dose extrapolation, which assumes effectively that one molecule of an agent will increase the risk of cancer, whereas, to my recollection, nongenotoxic carcinogens are considered to have thresholds and, of course, the suitability from a biological perspective of the assumption by FDA, essentially that linear low dose extrapolation is biologically accurate at the exceedingly low doses that are at issue in this litigation, **I think most scientists, cancer biologists would say that that is – those are overly conservative assumptions which are appropriate for a safety mandate of the FDA, but from the biological perspective of causation, they do not make biological sense.**

(Dr. Chodosh 9/29/21 Dep. Tr., 350:3-21 (emphasis added)).

> Q. And is it your opinion then, inconsistent with what the FDA has said, that there's a one in 8,000 risk, meaning one, maybe one additional case of cancer over the lifetimes of 8,000 people, isn't that your opinion, inconsistent with what the FDA has said?
>
> **THE WITNESS: In my opinion, no, in that what the purpose is of FDA's analysis is different than the purpose of my analysis.** My analysis revolves around the central question here, which is causation at the levels of

> exposure to which plaintiffs could theoretically have been exposed and determining causation based on a knowledge of the biology. **The FDA has a different mandate, which is precautionary, which is safety-based and is driven by regulatory issues, as well as it is by scientific issues. So our goals are different and, therefore, our methods will be different.**
>
> Q. And when examining the issue of a contamination in a drug product with a chemical like NDMA, which has been classified as a probable human carcinogen, wouldn't it be prudent to eliminate that chemical from the drug?
>
> **THE WITNESS: I am not here to give opinions about regulatory matters, which, as I've said multiple times is -- I am not an expert in regulatory matters.** What I was asked to address is could exposures, could theoretical exposures, at the levels that could even vaguely realistically have occurred in plaintiffs, is it biologically plausible that exposures of that level for the durations indicated and the time frame indicated could cause cancer in human beings, **that is a different purpose than what the FDA is doing.**

(Dr. Chodosh 9/29/2021 Dep. Tr., 327: 22-24; 328:1-24; 329:1-17 (emphasis added)).

This trial is governed by the FDA standards predicated on whether a risk is acceptable or not, the "overly conservative assumptions which are appropriate for a safety mandate of the FDA," which is not Dr. Chodosh's domain by his own admission. Thus Dr. Chodosh's general causation testimony does not address the

question of regulatory risk, and consequently does not fit the trial by his own admission.

Consistent with the distinction highlighted by Dr. Chodosh, Defendants have lost sight of the fact that they have already successfully precluded evidence of cancer causation at this trial, successfully arguing that "**any evidence of VCD users who developed cancer has no relevance to this case. This trial does not involve any personal injury claims by patients who took defendants' VCDs. Rather, the plaintiffs are third-party payors seeking economic loss damages**." (Defs.' Mot. *in Limine* (emphasis added) (ECF 2649-1, at p. 22)). If causation of cancer is precluded because irrelevant at this trial, then it cannot be allowed through a side door or back door.

Defendants' submission is also predicated on the illogical and obviously incorrect position that risk is not a factor in this trial, arguing: "The question for the jury in *this* trial is not whether the medication presented an 'acceptable' or 'unacceptable' risk; rather it is a question of whether the risk, if any, coupled with its undisputed efficacy, rendered the medication worthless. FDA decides what level of risk is 'acceptable' to be on the market, while patients and their physicians decide what level of risk is "acceptable" to an individualized patient." (Def. Br. at 2) (emphasis added). First, the fact that it was "unacceptable" to sell the contaminated

VCD's, as found by the FDA and admitted by every defendant, is relevant both to liability and damages—if the FDA had found the contamination to be acceptable for sale, that would be the lead in to every defense brief. Second, the fact that it was unacceptable to sell the pills because of the risk posed by the contamination with genotoxic nitrosamine impurities, is obviously relevant to value. Third, Defendants argue that even if the FDA says it is not acceptable to sell a drug due to unacceptable risk, a patient could still choose to purchase the pills; however, that is not what happened here. Once the contamination was finally disclosed by ZHP (after ZHP hid the contamination for as long as it could), no sales or purchases of the contaminated valsartan were permitted and a recall and import ban were instituted. Thus, in the real world, no patient was given the opportunity to buy the contaminated pills once the contamination was disclosed. Yet, the Court is permitting Defendants to retroactively argue that the pills had value due to their efficacy, and the jury will make the factual determination of value.

To be clear, Plaintiffs' case is built on what actually happened—the sale of pills contaminated with unapproved genotoxic impurities—NOT a counterfactual world where the contaminated pills were never sold, or where patients had the right to purchase the pills with disclosure of the contamination. The pills were sold here based on the false and deceptive misrepresentation that

what was being sold was the approved, compendium compliant form of the VCDs. In contrast, this is NOT a situation where a drug approved for sale with carefully worded disclosure of known risks in the approved label following full evaluation by the FDA of the risks was considered by the patient with input from the physician. Rather, this is a situation where the risk was not approved or disclosed.

Finally, Defendants present additional deposition excerpts that they argue implicate general causation. As with the prior submission, the excerpts are framed in terms of risk, and some of those relied on are not accurately quoted or were withdrawn by Plaintiffs.

For the Teva excerpts quoted by the Defendants:

- Barreto
  - 140:2-18 this is an incorrect citation by Defendants, that testimony was not designated. Defendants' quote appears to be to 142:13-17, which was designated.

- Binsol
  - 80:12-18 was withdrawn weeks ago.

- Nudelman
  - 179:13-180:12 was withdrawn weeks ago.

  - 190:2-14 was withdrawn weeks ago.

- Karlsson
  - 140:2-18 was already partially excluded by Judge Vanaskie, and Plaintiffs are willing to revisit and potentially withdraw the remaining designation.

For the Torrent excerpts, the Parties identified and held all designations related to general causation in abeyance based on Torrent's position that general causation was not precluded by the Court. Plaintiffs are prepared to delete those excerpts that implicate general causation; however, as with the ZHP and Teva excerpts, that should not include testimony regarding the risk posed by NDMA, since the risk posed by that substance is the reason for the recall. As previously argued, the use of a limiting instruction differentiating the unacceptable risk posed by NDMA, from the irrelevant question of whether the amount of contamination in the pills can cause cancer, will alleviate the risk of confusion. (ECF 2877).

CONCLUSION

For the foregoing reasons, Dr. Chodosh should not be permitted to testify in this economic loss trial governed by regulatory standards, and general causation should not be injected into the trial. The jury should determine the liability and damages questions based on what actually happened here—the sale of unapproved, contaminated VCDs, contrary to the representations by the Defendants that they were selling approved, compendium compliant valsartan—where nobody would have sold or paid for the pills if the contamination had been disclosed. The jury can

decide the question of value, taking into account Defendants' argument that the efficacy gave value, despite the contamination.

Respectfully,

ADAM M. SLATER

Cc: All counsel of record (via ECF)